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Lap-Band billboards finally get FDA's eyes

MICHAEL HILTZIK
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It has taken almost two years, but government regulators finally woke up to the idea that those 1-800-GET-THIN billboards plastered all over Southland freeways may be dangerous to your health.

That's the underlying meaning of the action announced Tuesday by the U.S. Food and Drug Administration against 1-800-GET-THIN and affiliated surgical services and clinics. The FDA warned the marketing company and the clinics that they're in violation of federal law by promoting the Lap-Band, a weight loss device that has been implanted in thousands of patients, through "false or misleading" advertising.

The letters, dated Dec. 9, require the targets to inform the FDA within weeks how they intend to revise their ads to comply with the law.

Two thoughts about the FDA's action come immediately to mind. One is: It's about time. The second: Other regulators should consider actions of their own.

For nearly two years, my colleagues and I have been reporting on the 1-800-GET-THIN ad campaign. In my very first column on the topic, in February 2010, I identified the people behind it as brothers Julian and Michael Omid, and reported that Julian's medical license had been revoked by the Medical Board of California and Michael's medical license had been placed on probation. (Michael's probation has since expired.)

Subsequently we reported on several deaths of Southland patients after surgeries performed at clinics that have been affiliated with the ad campaign, according to lawsuits, coroners' reports and other public records. So far the known toll is four, with a coroner's ruling still pending on the death of a fifth patient, who expired after being rushed to a hospital in September from the surgery center where she had just undergone the procedure.

We've reported on the shocking sanitary and safety conditions at one of the surgery centers affiliated with the ad campaign, and noted questions about whether the centers' insurance billing has been proper.

And we've reported that effective oversight of a potentially life-threatening procedure has been hampered by California's patchwork system of medical regulation, in which the medical board and the state Department of Public Health essentially pass the buck to each other over who should keep an eye on non-hospital surgery clinics like these.

Yet the 1-800-GET-THIN billboards, which have been hard to miss on Southland freeways for a couple of years, seem to have proliferated explosively in recent months, like a recrudescing, metastasizing cancer.

The FDA's action appears to be the first taken by a government agency against 1-800-GET-THIN over its feverish advertising, which seems to promote Lap-Band implantation as if it's a simple, short cosmetic procedure. It's not; it's major surgery.

The thrust of the FDA's warning letters is that it may be a violation of federal law for 1-800-GET-THIN and its affiliated clinics to downplay in their advertising the significant risks and complications of this surgery, including the risk of death, or to fail to make clear that to be truly effective, the Lap-Band needs to be accompanied by a significant change in the patient's eating habits and lifestyle.

Over the last year or so, GET-THIN's billboards have included disclaimers advising, for example, that Lap-Band surgery has certain "risks, side effects, and contraindications," and that you should check with your own doctor before undergoing the procedure. The FDA doesn't think that's nearly enough, especially because the disclaimers appear in such tiny type that they're "illegible."

To take action merely for its advertising against an enterprise that poses so many varied regulatory issues may strike some people as akin to prosecuting Al Capone for tax evasion, but there's more to it than that.

The FDA action is aimed at the very portal through which a very vulnerable population may be enticed into making unwise and uninformed choices about their healthcare. The prime targets of the Lap-Band advertisements, after all, are people who have tried other weight-loss methods and are now being led to believe that surgery is an easy option.

How have 1-800-GET-THIN and the other enterprises associated with the Omidis responded to the occasional scrutiny they've received? After Jonathan Fielding, director of the Los Angeles County Department of Public Health, complained about them to the FDA, they filed an administrative complaint against him with the county Board of Supervisors, asserting that he was biased against them because he was a shareholder in Johnson & Johnson, which markets a competing weight-loss device they don't use. Fielding said later that although county counsel told him he had no conflict of interest, he would recuse himself from matters involving weight-loss devices.

When the Los Angeles County coroner blamed the death of Tamara Walter, a Lap-Band patient, at least partially on the "suboptimal" anesthesiology care she had received at a clinic affiliated with 1-800-GET-THIN, the clinic smeared the coroner's anesthesiology expert, accusing her in a letter to the coroner of a conflict of interest because she had once worked at UCLA, which they said "competes directly" with the Lap-Band clinic. (To his credit, the medical examiner, Dr. Lakshmanan Sathyavagiswaran, essentially told them to go jump in the lake. The consultant's work, he said, was "both thorough and accurate.")

And they've sued me and my colleagues at The Times for reporting about them. So far, three of these lawsuits against us have been thrown out of court by state and federal judges. The plaintiffs have appealed the dismissals and filed more suits against us and commenters on our website.

The public record is brimming with material -- including complaints of wrongful death, negligence and irregularities in billing practices -- that could fall well within the jurisdiction of several state regulatory agencies. It may be that the FDA has fired the first shot in what could be a barrage. Certainly the message communicated by the FDA warning letters is of paramount importance to Southland motorists: When you pass a billboard advertising 1-800-GET-THIN, keep your eyes on the road.

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Michael **Hiltzik**'s column appears Sundays and Wednesdays. His latest book is "The New Deal: A Modern History." Reach him at mhiltzik@latimes.com.

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